REMARKS

In response to the final Office Action mailed on November 1, 2006, Applicants submit this Amendment After Final.

As an initial matter, Applicants would like to thank Examiner Willse for allowing and conducting the telephonic interview of January 11, 2007. In the interview, Applicants and the Examiner discussed the rejection of claims 26-30, 36-41, 43, and 44 over Melvin (U.S. Patent No. 5,957,977). In particular, Applicants contended that Melvin fails to disclose, for example, holding a structure of a heart in a geometrically altered state, so as to promote closure of an in situ heart valve. The substantive matters discussed in the interview with regards to the Melvin reference are incorporated in the remarks as set forth below. In response to Applicants' contention, the Examiner agreed to review the Melvin reference to evaluate Applicants' arguments.

In the Office Action, the Examiner rejected claims 26-30 and 36-44 under either 35 U.S.C. § 102(e) or 35 U.S.C. § 103(a) based on Melvin. The Examiner made the rejections final.

By this Amendment, Applicants amend claims 26, 29, 30, 36, and 40, and cancel claim 27. Accordingly, claims 26, 28-30, and 36-44 are currently pending. Of these claims, claims 26 and 36 are independent.

Applicants respectfully traverse the rejections of claims 26-30, 36-41, 43, and 44 under 35 U.S.C. § 102(e).

Independent claim 26 is drawn to a method of treating valvular dysfunction of an in situ valve of a heart, and independent claim 36 is drawn to a method of treating a heart. Each of these claims requires displacing a portion of a heart wall to a displaced state and holding the portion of the heart wall in the displaced state so as to reduce a transverse dimension of a portion of the heart.

Melvin discloses a mechanical activator device that assists in pumping blood from a heart chamber during systole and then, by design, returns the volume of the chamber back to its original volume for refilling of blood during diastole. Melvin, however, has no teaching or suggestion of displacing a portion of a heart wall to a displaced state and holding the portion of the heart wall in the displaced state so as to reduce a transverse dimension of a portion of the heart.

More particularly, Melvin discloses a mechanical activator device that includes portions internal to the heart and portions external to the heart. As best shown in Figure 2 of Melvin, the internal portions include an internal stint 52 that comprises a septal stint 54, a ring 56, and a ring 58. The septal splint 54 contacts and supports the septum outside of the left ventricle. The rings 56 and 58 connect to the septal splint 54 and are placed adjacent valves in the left atrium and left ventricle, respectively. The components of the stint 52 are elastic so that stint 52, as will be explained, assists in returning the chamber to its original volume for the diastolic portion of the cardiac cycle.

The stint 52 connects to the external portion of the device via cords 86 that extend through the heart wall. As shown, for example, in Figure 5A, the external portion includes a yoke 70 and an activator 74. The yoke 70 is placed around the exterior surface of the heart and attaches to the activator 74. The activator 74 includes a hydraulic arm 75 and bands 84 secured to the yoke 70. Arm 75 attaches to a pump P for controlling fluid volume in arm 75 to alter the shape of arm 75.

In operation, when arm 75 is altered from the relaxed condition (Figure 7A) to the activated condition (Figure 7B), arm 75 and bands 84 deform and apply pressure against the exterior heart wall, reduce chamber volume, and thereby assist in the systolic portion of the cardiac cycle to pump blood. See col. 7, ll. 40-49. Following activation during systole, arm 75 and bands 84 release from the heart and return to their relaxed condition. See, e.g., col. 3, ll. 40-42. Melvin teaches that the stint 52 and yoke 70 "assist[] in returning the deformed portion of the natural heart 10 back to its pre-activation volume so that it can refill with blood during the diastolic portion of the cardiac cycle." See col. 7, ll. 50-57.

Melvin therefore has no suggestion of displacing a portion of a heart wall to a displaced state and *holding* the portion of the heart wall in the displaced state so as to reduce a transverse dimension of a portion of the heart. To the contrary, Melvin explicitly teaches that the disclosed device, by design, dynamically returns the heart to its original, unrestrained volume for refilling of blood during diastole.

Furthermore, in the Office Action, the Examiner contends that the passing of cords 86 through cardiac tissue, the atriotomy and ventriculotomy steps of implanting the disclosed device, the ability of yoke 70 to provide equalized pressure over the irregularities in the epicardial surface of a natural heart, and tightening of cords 86, correspond to altering a geometry of heart structure. Specifically, the Examiner alleges that "[h]eart structure is clearly altered by the passage of cords 86 through cardiac tissue and by the atriotomy and ventriculotomy steps (column 8, lines 8-18) and is also altered by virtue of the 'equalized pressure over the irregularities in the epicardial surface' (column 5, lines 40-44) and the tightening of the cords 86 (column 8, lines 40-

43)." Insofar that these allegations may be relevant to the currently amended claims, Applicants respectfully disagree.

First, the passage of cords 86 through cardiac tissue clearly does nothing to displace a heart wall so as to reduce a transverse dimension of a portion of the heart.

Second, the atriotomy and ventriculotomy steps recited by Melvin relate to the surgical opening of an atrium and ventricle, respectively, and Melvin does not disclose or suggest that these surgical procedures displace a heart wall portion to result in a reduction of a transverse dimension of a portion of the heart, or hold that heart wall portion in the displaced state to promote closure of an in situ valve. The portions of Melvin cited by the Examiner do not include such teachings. Column 8, lines 8-18, states:

> Through an aortotomy and an interatrial groove left atriotomy, the first and second rings 56 and 58, respectively, are inserted and sutured in position. Preferably, the first ring 56 is positioned suprajacent the mitral annuli and the second ring 58 is positioned subjacent the aortic annuli.
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> The interlocking struts of the septal frame 53 (e.g., anterior[] strut 62, a posterior strut 63, and basal strut 64) are inserted into the right ventricle 14 through an apical ventriculotomy, a right atriotomy with partial temporary detachment of the septal tricuspid leaflet of the tricuspid valve, and an outflow tract ventriculotomy, respectively.

This teaching relates only to the implantation procedures for the septal stint 54, ring 56, ring 58.

Third, the ability of yoke 70 to provide equalized pressure over the irregularities in the epicardial surface of a natural heart pertains to the yoke 70 being able to apply pressure equally to all portions of the external surface of the heart during systolic activation of the Melvin device. Column 5, lines 40-44, states that "the yoke 70 can include a gel-filled cushion portion 80 that is positioned immediately adjacent exterior surface of the natural heart 10 for providing equalized pressure over the irregularities in the epicardial surface of the natural heart 10." This teaching includes no discussion of displacing a heart wall and holding the wall in the displaced position to reduce a transverse dimension of a portion of the heart.

As to the tightening of cords 86, the cited portion, column 8, lines 40-43, states that "[c]ords 86 are tightened to render the intrinsically flexible stint 52 relatively taut and control bulging, preferably in a rightwardly direction." This teaching relates only to ensuring the septal splint 52 remains in its implanted position and configuration, and to prevent deformation of the splint 52 caused by bulging. It includes no discussion of displacing a heart wall and holding the wall in the displaced position to reduce a transverse dimension of a portion of the heart.

Accordingly, Melvin fails to teach each and every element of independent claims 26 and 36, and Applicants respectfully request that the rejections of these claims and their dependents be reconsidered and withdrawn.

Applicants respectfully traverse the rejection of claim 42 under 35 U.S.C. § 103(a). Even assuming that the Examiner's allegations regarding anchor pads being well known in the art at the time of the present invention and their use would have been obvious, which Applicants do not necessarily concede, claim 42 is allowable over Melvin at least due to its dependence from independent claim 36.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 26, 28-30, and 36-44 in condition for allowance. Applicants submit that the proposed Amendments of claims 26, 29, 30, 36, and 40 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of this Amendment would allow Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of this Amendment will place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims. If the Examiner would like to discuss this case, he is invited to contact the undersigned at (202) 408-4140.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: January 31, 2007

By: Leslie Bookoff
Leslie I. Bookoff
Reg. No. 38,084